JONES DAY

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JP017692:ceb

January 19, 2018

VIA CERTIFIED MAIL –
RETURN RECEIPT REQUESTED

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

RE: FOIA Request

Dear Sir or Madam:

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, as amended ("FOIA"), the requesting party requests the information specified below. My contact information is:

Jeffrey J. Jones
Jones Day
150 W. Jefferson, Suite 2100
Detroit, Michigan 48226
Telephone: (313) 230-7950
Fax: (313) 230-7997

Please provide the information by email if practicable to: jjjones@jonesday.com. The requesting party agrees to pay fees associated with this request up to one thousand dollars ($1,000.00) without further notice from the responding agency.

Requested Information

1. Copies of any documents, testing, scientific literature, data, analyses, or communications that discuss, support, analyze, contradict, or refer to the Environmental Protection Agency's Registration Review of the insecticide, chlorpyrifos-methyl (PC Code 059102) (EPA Reg. No. 264-992).

2. Copies of any documents, testing, scientific literature, data, analyses, or communications that discuss, support, analyze, contradict, or refer to the following references in the Environmental Protection Agency's Registration Review Memorandum of the insecticide, chlorpyrifos-methyl (PC Code 059102), including copies of the references themselves:

Beavers, J.B.; Fink, R.; Brown, R. (1978) Final Report: Eight-Day Dietary LC50--Bobwhite Quail: Project No. 103-186. U.S. EPA MRID 00039223;

Bryson, A.M. 1992. A Study of the Effect of Technical Reldan on the Pregnancy of the Rat. Huntingdon Research Centre Ltd. Laboratory Study ID: GHE-413. MRID 44680603;

U.S. EPA, 2015. Email communication from D. Atwood, Biological and Economic Analysis Division. March 26, 2015;

Cunningham and Schafer, 1968. Starling and Redwinged Blackbird. 1968. EPA Ascension No. 242149, Report #3a. U.S. EPA MRID 00028755;

Saltatos, et al. 1982. Factors Involved in the Differential Acute Toxicity of the Insecticides Chlorpyrifos and Methyl Chlorpyrifos in Mice. Toxicology and Applied Pharmacology, 65, pp. 144 – 152;

Verma, et al. 2012. Acute Oral Toxicity Study of Chlorpyrifos Methyl TGAI in Rats. HAI Research Foundation. Laboratory Project Study Number 401-1-01-4229. MRID 48868101.

3. Copies of any documents, testing, scientific literature, data, analyses, or communications that discuss, support, analyze, contradict, or refer to the Environmental Protection Agency's determination that "even if terrestrial vertebrates were exposed to seeds treated at the maximum chlorpyrifos-methyl concentration (*i.e.*, 3ppm), potential risk would be low." *See* Environmental Protection Agency Registration Review Memorandum of the insecticide, chlorpyrifos-methyl (PC Code 059102) at 2.

5. Copies of any documents, testing, scientific literature, data, analyses, or communications that discuss, support, analyze, contradict, or refer to "Appendix A. TREX Modeling for Exposure to Eating Treated Seed," as referenced in the Environmental Protection Agency's Registration Review Memorandum of the insecticide, chlorpyrifos-methyl (PC Code 059102).

For the EPA's convenience, enclosed please find the above-referenced EPA Memorandum ("Chlorpyrifos-methyl - Preliminary Ecological Risk Assessment and Effects Determination in Support of Registration Review" (PC Code 059102)).

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Please note that the terms "documents" and "communications" are used in the broadest possible sense. The conjunction "or" should always be interpreted in a manner that includes the most possible information, documents, or communications. Please provide responses to this request as soon as practicable. If any request, or portion thereof, is denied, please inform me in writing of the specific reasons for the denial. If part of any document responsive to this request is claimed to be exempt from disclosure, please provide the remaining non-exempt portions.

Thank you for all of your assistance with regard to this matter. If you have any questions, please let me know.

Very truly yours,

Jeffrey J Jones / per authority CEB

Jeffrey J. Jones
Counsel for The Scotts Miracle-Gro Company, and The Scotts Company LLC

Enclosure

NAI-1503329389v2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

PC Code: 059102
DP Code: 426737
April 13, 2015

MEMORANDUM

SUBJECT: Chlorpyrifos-methyl - Preliminary Ecological Risk Assessment and Effects Determination in Support of Registration Review

TO: Joel Wolf, Chemical Review Manager
Kevin Costello, Chief
Risk Management and Implementation Branch 2
Pesticide Re-evaluation Division (7508P)

FROM: Rosanna Louie-Juzwiak, Risk Assessment Process Leader
Environmental Risk Branch III
Environmental Fate and Effects Division (7507P)

ROSANNA LOUIE-JUZWIAK
2015.04.13
11:43:12 -04'00'

THROUGH: Dana Spatz, Chief
Environmental Risk Branch III
Environmental Fate and Effects Division (7507P)

REVIEWED BY: James Hetrick, Ph.D., Senior Advisor
Melissa Panger, Ph.D., Senior Scientist
Environmental Risk Branch III
Environmental Fate and Effects Division (7507P)

MELISSA PANGER

Digitally signed by MELISSA PANGER
DN: c=US, o=U.S. Government, ou=USEPA, ou=Staff, cn=MELISSA PANGER, dnQualifier=0000025251
Date: 2015.04.13 12:38:09 -04'00'

The Environmental Fate and Effects Division (EFED) has completed the preliminary ecological risk assessment and federally listed, threatened, and endangered species (also referred to as "listed" species) effects determination in support of the Registration Review of the insecticide, chlorpyrifos-methyl (PC Code 059102). Chlorpyrifos-methyl is registered as an insecticide used to target and kill a variety of stored grain insects including beetles, weevils, moths, and grain borers. The registered uses of chlorpyrifos-methyl are limited to indoor applications made to the interior of empty grain storage bins or warehouses, or, directly to harvested small grains just prior to storage. Virtually no exposure to non-target organisms is expected to occur when this product is used as labeled; therefore, risk is not expected to non-target organisms, including listed species.

ASSESSMENT

Chlorpyrifos-methyl is registered in one end-use product (Storcide II Grain, Bin and Warehouse Insecticide end use product; EPA Reg. No. 264-992), and the technical product (Reldan F Insecticidal Chemical; EPA Reg. No. 62719-42) for treatment of grains in storage bins and warehouses. Chlorpyrifos-

methyl is applied indoors to empty storage grain bins or warehouses with one application per year by sprayer or automatic sprayer at a rate of 0.0253 pound of active ingredient per 1,000 square feet. Chlorpyrifos-methyl can also be applied indoors directly to small grains prior to storage, to achieve a concentration of up to 3 parts per million. Based on available, but limited recent usage data provided by the Biological and Economic Analysis Division, approximately 4,500 pounds of chlorpyrifos-methyl is applied annually (EPA, 2015).

The labeled indoor uses and application methods of chlorpyrifos-methyl significantly limits any potential direct or indirect exposure (including drift and runoff) to outdoor terrestrial areas. In addition, these use patterns are unlikely to result in exposure to aquatic resources or groundwater. Because of the indoor use pattern and very low potential for outdoor exposure to non-target species, only limited data have been submitted for this chemical.

Although chlorpyrifos-methyl is an organophosphate, the available information indicates that when compared to its closely-related structural analog chlorpyrifos, chlorpyrifos-methyl is of lower toxicity to vertebrates (Beavers, 1978) (Saltatos, *et al.*, 1982). With the exception of potential toxicity to invertebrates (as expected for an insecticide), chlorpyrifos-methyl is generally less toxic than other organophosphates (*e.g.*, chlorpyrifos).

Other than exposure to the target pest inside of the storage bins, the only potential exposure to non-target organisms would be treated seeds that were subsequently used for planting, which would occur several months after the initial treatment. A cursory screen was conducted using the lowest reported avian acute (100 mg/kg/day) (MRID 00027855), acute oral mammalian (5,000 mg/kg body weight) (MRID 48868101), and a chronic mammalian endpoint (body weight gain) from a developmental study (50 mg/kg body weight) (MRID 44680603). This analysis showed that even if terrestrial vertebrates were exposed to seeds treated at the maximum chlorpyrifos-methyl concentration (*i.e.*, 3 ppm), potential risk would be low (see Appendix A for the T-REX analysis).

CONCLUSIONS

Based on the use pattern whereby exposure from use of chlorpyrifos-methyl is expected to be negligible, and the low potential for risk if exposures occur via planted treated seeds, EPA concludes that the currently registered uses of chlorpyrifos-methyl are not reasonably expected to cause direct or indirect effects to federally listed threatened and endangered species. A *No Effect* determination is made for all listed species, as well as a *No Habitat Modification* determination for all designated critical habitats for the currently registered uses of chlorpyrifos-methyl.

ENDOCRINE DISRUPTOR SCREENING PROGRAM

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision for chlorpyrifos-methyl, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), chlorpyrifos-methyl is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[1] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[2]

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[1] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

[2] http://www.epa.gov/endo/

References:

Beavers, J.B.; Fink, R.; Brown, R. (1978) Final Report: Eight-Day Dietary LC_{50}--Bobwhite Quail: Project No. 103-186. U.S. EPA MRID 00039223.

Bryson, A.M. 1992. A Study of the Effect of Technical Reldan on the Pregnancy of the Rat. Huntingdon Research Centre Ltd. Laboratory Study ID: GHE-413. MRID 44680603.

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Verma, et al. 2012. Acute Oral Toxicity Study of Chlorpyrifos Methyl TGAI in Rats. HAI Research Foundation. Laboratory Project Study Number 401-1-01-4229. MRID 48868101.

Appendix A. TREX Modeling for Exposure to Eating Treated Seed

A cursory analysis was conducted using the lowest reported avian acute (100 mg/kg/day) (MRID 00027855), acute oral mammalian (5,000 mg/kg body weight) (MRID 48868101), and a chronic mammalian endpoint (body weight gain) from a developmental study (50 mg/kg body weight) (MRID 44680603).

The application rate for the end use product (EPA Reg. No. 264-992) for wheat is 12.4 fluid ounces of product per 1,000 bushels, to achieve a 3 ppm concentration on seed.

Chemical Name:	chlorpyrifos methyl
Seed Treatment? (Check if yes)	Yes, Seeding rate of 156.0 lb/acre
% A.I. (leading zero must be entered for formulations <1% a.i.):	21.60%
Application rate (fl oz/cwt)	0.02
Half-life (days):	35
Application Interval (days):	0
Number of Applications:	1
Are you assessing applications with variable rates or intervals?	no

Reported Endpoints		Tested Body Weight (g)	Adjusted LD_{50}	Size class for adjusted LD_{50}
Avian LD_{50}:	100.00	29	94.58	Small (20g)
Avian repro. NOAEC:	0.00		120.40	Medium (100g)
			170.07	Large (1000g)
Mammalian LD_{50}:	2000.00	350	4395.66	Small (15g)
Mammalian NOAEL:	6.60		3556.56	Medium (35g)
			1538.32	Large (1000g)
		Adjusted NOAEL for Mammals		
		Small (15g)	109.89	
		Medium (35g)	88.91	
		Large (1000g)	38.46	

Animal Size	Crop	Maximum Application Rate (lb a.i./A)	Maximum Seed Application Rate (mg a.i./kg seed)	Avian Nagy Dose (mg a.i./kg-bw/day)	Mammalian Nagy Dose (mg a.i./kg-bw/day)	Available AI (mg ai. ft-2)
Small	wheat, all or unspecified	<0.01	2.81	0.71	0.60	0.00
Medium				0.41	0.41	
Large				0.18	0.10	

Crop	Risk Quotients†					
	Avian (20 g)			Mammalian (15 g)		
	Acute (# 1)	Acute (# 2)	Chronic	Acute (# 1)	Acute (# 2)	Chronic
wheat, all or unspecified	0.01	<0.01	N/A	<0.01	<0.01	0.01
	Avian (100 g)			Mammalian (35 g)		
	Acute (# 1)	Acute (# 2)	Chronic	Acute (# 1)	Acute (# 2)	Chronic
wheat, all or unspecified	<0.01	<0.01	N/A	<0.01	<0.01	<0.01
	Avian (1000 g)			Mammalian (1000 g)		
	Acute (# 1)	Acute (# 2)	Chronic	Acute (# 1)	Acute (# 2)	Chronic
wheat, all or unspecified	<0.01	<0.01	N/A	<0.01	<0.01	<0.01

† Acute RQ #1 = (mg a.i. /kg-bw/day) / LD_{50} N/A = not assessed

Acute RQ #2 = mg a.i. ft-2 /(LD_{50}*bw)

Avian Chronic RQ = mg kg-1 seed / NOAEL

Mammalian Chronic RQ = mg a.i./kg-bw/day / adjusted NOAEL